DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 5

Delegations of Authority and Organization; Center for Veterinary Medicine

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the delegations of authority with respect to animal drugs to incorporate provisions for feed mill licensing in accordance with the Animal Drug Availability Act (ADAA) of 1996. The ADAA amended some sections of the Federal Food, Drug, and Cosmetic Act (the act) to require a single facility license for the manufacturer of medicated feeds containing approved new animal drugs, rather than multiple medicated feed applications for each feed mill, as previously required by the act. This notice also updates position and component titles and associated delegations of authority within the Center for Veterinary Medicine (CVM) as a result of organizational restructuring.

EFFECTIVE DATE: December 22, 1998.

FOR FURTHER INFORMATION CONTACT:

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Loretta W. Davis, Division of Management Systems and Policy (HFA–340), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4809.

SUPPLEMENTARY INFORMATION: FDA is amending the delegations of authority in subpart B of part 5 (21 CFR part 5) in order to revise §§ 5.83 and 5.84 to include additional authorities with regard to the approval of the medicated feed mill license applications. The ADAA (Pub. L. 104–250) amended section 512(a) and (m) of the act (21 U.S.C. 360b(a) and (m)). Moreover, this final rule reflects specific organizational, position, and title revisions within CVM due to organizational restructuring of specific components.

Further redelegation of the authorities delegated is not authorized at this time. Authority delegated to a position may be exercised by a person officially designated to serve in such position in an acting capacity or on a temporary basis.

List of Subjects in 21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 5 is amended as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. The authority citation for 21 CFR part 5 continues to read as follows:

Authority: 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 138a, 2271; 15 U.S.C. 638, 1261–1282, 3701–3711a; 15 U.S.C. 1451–1461; 21 U.S.C. 41–50, 61–63, 141–149, 321–394, 467f, 679(b), 801–886, 1031–1309; 35 U.S.C. 156; 42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 264, 265, 300u–300u–5, 300aa–1; 1395y, 3246b, 4332, 4831(a), 10007–10008; E.O. 11921, 41 FR 24294, 3 CFR, 1977 Comp., p. 124–131; E.O. 12591, 52 FR 13414, 3 CFR, 1988 Comp., p. 220–223.

2. Section 5.83 is amended by revising the section heading, paragraphs (c)(1) and (c)(2), and paragraph (d) to read as follows:

§ 5.83 Approval of new animal drug applications, medicated feed mill license applications and their supplements.

* * * * *

(c) * * *

(1) The Director, Division of Human Food Safety, Office of New Animal Drug Evaluation, CVM.

(2) The Director, Division of Epidemiology and Surveillance, Office of Surveillance and Compliance, CVM.

(d) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to the approval of medicated feed mill license applications for the manufacture of animal feeds containing new animal drugs pursuant to section 512(m) of the act, as amended by the Animal Drug Availability Act of 1996 (Pub. L. 104–250):

(1) The Director and Deputy Director, CVM.

(2) The Director, Division of Animal Feeds, Office of Surveillance and Compliance, CVM.

(3) The Leader, Medicated Feeds Team, Division of Animal Feeds, Office of Surveillance and Compliance, CVM.

(4) The Medicated Feeds Specialist, Medicated Feeds Team, Division of Animal Feeds, Office of Surveillance and Compliance, CVM.

3. Section 5.84 is amended by revising the section heading and paragraphs (a)(1) and (a)(3) to read as follows:

§ 5.84 Issuance of notices, proposals, and orders relating to new animal drugs and medicated feed mill license applications.

(a) * * *

(1) Issue notices of opportunity for a hearing on proposals to refuse approval or to withdraw approval of new animal drug applications, and supplements thereto, for drugs for animal use and proposals to refuse approval or to revoke approval of medicated feed mill license applications, and supplements thereto, submitted pursuant to section 512(m) of the Federal Food, Drug, and Cosmetic Act, as amended by the Animal Drug Availability Act of 1996 (Pub. L. 104–250).

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(3) Issue proposals and orders to revoke and amend regulations for new animal drugs for animal use and medicated feed mill licenses, corresponding to said act on such applications.

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Dated: December 14, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 658

RIN 2125–AE47

Truck Size and Weight; Technical Corrections

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Final rule; technical corrections.

SUMMARY: This document amends truck size and weight regulations by changing the definition of automobile transporters to include those transporting towed vehicles and truck camper units and extending the Interstate System axle weight exemption for public transit buses to October 1, 2003, as provided by the Transportation Equity Act for the 21st Century (TEA–21), Pub. L. 105–178, 112 Stat. 107. Five additional technical corrections are also being made, to add Alligator Alley (I–75) to the National Network (NN) listing in Florida; clarify that a State's grandfathered weight limits for divisible vehicles or loads on the Interstate System are permanently vested; clarify that the length of cargo carrying units subject to the freeze in the Intermodal Surface Transportation Efficiency Act of